AMENDED CLAIMS

[received by the International Bureau on 04 October 2005 (04.10.2005);
original claims 1-23 replaced by amended claims 1-14 (2 pages)]

We claim:

1. A crystalline form R of atorvastatin hemi calcium exhibiting an XRD spectrum comprising peaks at about 8.62, 10.16 and 19.32 degrees two-theta.

2. The crystalline form R of atorvastatin hemi calcium of claim 1, further comprising peaks at about 3.6, 8.24, 18.12, 18.36, 20.44, 20.82, 21.22 and 23.82 degrees two-theta.

3. A process for preparing crystalline form R of atorvastatin hemi calcium and hydrates thereof according to any of the claims above, comprising dissolving crude atorvastatin hemi calcium in a mixture of tetrahydrofuran and methanol, and precipitating with water to obtain a crystalline form R of atorvastatin hemi calcium.

4. The process according to claim 3, wherein crude atorvastatin hemi calcium contains unreacted compounds, side products or other impurities.

5. The process according to claim 3, wherein the mixture of crude atorvastatin hemi calcium and solvent system is heated to reflux.

6. The process according to claim 5, wherein the crystalline form R of atorvastatin hemi calcium and hydrates thereof is isolated by cooling the mixture to a temperature of about 20 to about 40°C.

7. The process according to claim 3 to 6, wherein tetrahydrofuran, methanol and water are used in a volume ratio of about 1:1:4.

8. A process for the preparation of a stabilized amorphous form of atorvastatin hemi calcium, comprising dissolving the crystalline form R of atorvastatin hemi calcium and hydrates thereof in a solvent, and adding the anti-solvent to the resulting solution, wherein an antioxidant is added to the atorvastatin hemi calcium solution to obtain stabilized amorphous atorvastatin hemi calcium.

9. The process according to claim 8, wherein an antioxidant is selected from the group consisting of butylated hydroxyanisole, butylated hydroxytoluene and tertiary-butylated hydroquinone.

10. A pharmaceutical composition comprising a crystalline form R of atorvastatin hemi calcium or hydrates thereof according to claims 1 or 2, along with pharmaceutically acceptable excipients, diluents and carriers.

11. A method for treatment or prevention of hyperlipidemia, hypercholesterolemia, Alzheimer's disease atherosclerosis, xanthoma and in synergism with other drugs for treatment of phytosterolemia lipase deficiency and the like, which comprises administering to a patient in need thereof, a therapeutically effective amount of crystalline form R of atorvastatin hemi calcium or hydrates thereof according to claims 1 or 2.

12. The use of the crystalline form R of atorvastatin hemi calcium and hydrates thereof according to claims 1 or 2 in the manufacture of a medicament for the treatment or prevention of hyperlipidemia, hypercholesterolemia, Alzheimer's disease, atherosclerosis, xanthoma and in synergism with other drugs for treatment of phytosterolemia lipase deficiency and the like.

13. A crystalline atorvastatin hemi calcium form R or a hydrate thereof having a powder XRD pattern substantially as depicted in FIG. 1.

14. A crystalline atorvastatin hemi calcium form R or a hydrate thereof having IR spectrum substantially as depicted in FIG. 2.